K083482

510(k) Summary

APR - 2 2009

Submitted by:

Jim Ferguson
Quality Systems Manager
Cook Vascular, Incorporated
1186 Montgomery Lane
Vandergrift, Pa 15690
724-845-8621, XT 2227
April 10, 2006

Device:

Trade name:	**Cook Vascular VITAL-JECT™ Power Injectable Safety Infusion Set**
Proposed Classification:	**Intravascular Administration Set, 880.5440**

Predicate Devices:

The Cook Vascular VITAL-JECT™ Power Injectable Safety Infusion Set is similar in terms of intended use, and exactly the same as materials of construction and technology characteristics to the predicate devices that have been found substantially equivalent.

Device Description:

The Cook Vascular VITAL-JECT Power Injectable Safety Infusion Set is intended to administer solutions and medications into vascular implant ports. In addition, to minimize the risk of accidental needle stick after use, the attached safety guard fully encapsulates the needle when manually activated during withdrawal.
When used with a power Injectable vascular implant port, the Cook Vascular Safety Infusion Set is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s using contrast with a maximum viscosity of 11.8cP.
The device consists of a protector cap, female luer lock, PVC tubing, two each 4 inch tubing length, a pinch clamp, with a needle free y-site, a butterfly wing, a safety needle guard, an AISI 304 (19 ga) stainless steel needle and a needle sheath.

Substantial Equivalence:

The components and the processes used to manufacture these solution administration sets are the exact same as the currently legally marketed by Command Medical, HuberPRO™ Safety Huber Infusion Set. (K033515). The packaged Infusion set will be supplied from Command Medical and Cook Vascular will label, sterilize and market the product.

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Test Data:

The **Cook Vascular, Inc. VITAL-JECT™ Power Injectable Safety Infusion Set** was subjected to the flowing tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Dynamic Failure Flow Test
2. Instantaneous Burst Test
3. Static Pressure Test
4. Life Cycle Power Injection Test

An analysis of the test results lead to the conclusion that the Vital-Ject infusion set is capable of being power injected at the establish 5mL/s with a given media viscosity of 11.8cP.

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a **VITAL-JECT™ Power Injectable Safety Infusion Set**

Sterilization Information:

The infusion sets were validated to a standard 100% ETO Cook sterilization cycle with the Infusion Port Universal Tray set. Bioburden Testing, Endotoxin Testing, EO residual testing, and sterility testing was performed. EO Residual testing and sterility testing was performed on the Infusion Port body (model IP-S6110) which has been determined to provide the greatest challenge when testing for EO residuals and sterility. The test results for Endotoxin testing, EO Residual testing and sterility testing all indicated acceptable results. Bioburden testing on the infusion sets using combination membrane filtration and 3-layer pour plates was used. All individual tested infusion sets were within specification with the exception of one. The cfu/device for this sample measured 1126. This result is above the alert level of 300 colony forming units per device. The other eight test samples cfu level ranged from 3 to 56 cfu/device. The average Bioburden level for all nine samples is 149 cfu with is far below the 300 cfu alert limit. In addition, the sterilization validation and Endotoxin results for the Infusion sets indicate that the established sterilization process is capable of producing acceptable results.

Based on the fact the Cook Vascular, Inc. VITAL-JECT Power Injectable Safety Infusion Set utilizes the same design, components and manufacturing processes as currently legally marketed products, the Cook Vascular, Inc. VITAL-JECT Power Injectable Safety Infusion Set is safe and effective when used as intended.

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Device Description

The components and the processes use to manufacture these solution administration sets are the same as the currently legally marketed by Command Medical, K033515 HuberPRO™ Safety Huber Infusion Set.

Cook Vascular, Inc. will label and sterilize the final product. The proposed device is manufactured exactly the same as the currently marketed device. (K033515)

Drawings are included in Attachment B.

Functional Features

A comparison of features and specifications of the **Cook Vascular, Inc. VITAL-JECT™ Power Injectable Safety Infusion Set** are included on page 7.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2009

Mr. Jim Ferguson, Jr.
Cook Vascular Incorporated
1186 Montgomery Lane
Vandergrift, Pennsylvania 15690

Re: K083482
Trade/Device Name: Cook Vascular VITAL-JECT™ Power Injectable Safety Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 12, 2009
Received: March 17, 2009

Dear Mr. Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

K083482

510(k) Number: _____

Device Name: **Cook Vascular, Inc. Vital-Ject Power Injectable Safety Infusion Set**

Indications for Use:

The Cook Vascular VITAL-JECT Power Injectable Safety Infusion Set is intended to be used to administer solutions and medications into vascular implant ports. When used with a power Injectable vascular implant port, the Cook Vascular Safety Infusion Set is indicated for power injection of contract media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s using contrast with a maximum viscosity of 11.8cP.

In addition, to minimize the risk of accidental needle stick after use, the attached safety guard fully encapsulates the needle when manually activated during withdrawal.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083482

Prescription Use X OR Over-The-Counter Use ____